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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,431	12/12/2003	Prashant Iyer	10150.200-US	3881

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NEW YORK, NY 10110

EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,431

Applicant(s)

IYER ET AL.

Examiner

Allison M Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Application

Claims 1-18 are pending in the current application.

Priority

Acknowledgement is made of applicant's claim for priority to provisional application

60/434,722, filed 12/19/2002.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: CLOUD-POINT EXTRACTION OF ENZYMES AND POLYPEPTIDES FROM A FERMENTATION BROTH USING A NON-IONIC SURFACTANT.

Claim Objections

Claim 1 is objected to because of the following informalities: grammatical error, Claim 1, step (i) should read, "adjusting the pH close to the pI of the polypeptide of interest." Claim 17, step (i) should read, "the fermentation broth is diluted (0 to 100%) for viscosity reduction before adjusting the pH close to the pI of the polypeptide of interest." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for extracting hydrophobic polypeptides, does not reasonably provide enablement for extracting all polypeptides, especially water soluble polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims a method of extracting a polypeptide of interest from a fermentation broth by separating the fermentation broth into liquid-liquid-solid fractions and recovering the surfactant-rich top phase. However, because applicant only claims recovering the surfactant-rich top phase, they are only enabled for extraction of the hydrophobic polypeptides found in the surfactant-rich top phase; they are not enabled for extraction of any polypeptide. Terstappen et al teach in separations using cloud point extraction to a multi-phase separation system, only the integral membrane proteins partition into the coacervate phase (which applicant calls the surfactant-rich top phase); water soluble proteins remain in the detergent-depleted phase (See Pg. 264). Though Terstappen et al describes the separation of proteins, one of ordinary skill in the art can extend this teaching to the differential separation of all hydrophilic and hydrophobic polypeptides, wherein only hydrophobic polypeptides would be found in the coacervate phase

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(surfactant-rich top phase) and the remaining hydrophilic polypeptides would remain in the detergent-depleted phase. This separation is inherently based on the hydrophobic/hydrophilic properties of molecules. Thus, applicant's method is limited to the recovery of polypeptides from the surfactant-rich top phase; it does not provide a step or teaching for recovering polypeptides from the detergent-depleted phase; therefore their scope is limited to those hydrophobic polypeptides that could be successfully extracted from the surfactant-rich top phase. Claims 2-18 have the limitation of claim 1 and are thus rejected on the same basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 1 is directed to a method of extracting a polypeptide of interest from a fermentation broth comprising: i) adjusting the pH close to the pI of the polypeptide of interest; ii) adding a non-ionic surfactant with a hydrophile-lipophile balance (HLB) of 12 or lower; iii) cooling the mixture for solubilization and incubating at above cloud point for extraction; iv) phase separating at below cloud point to obtain liquid-liquid-solid fractions; and v) recovering the surfactant rich top phase containing the polypeptide of interest. The term "close" in step i) of the method is indefinite, as it does not provide any reasonable limitations defining how similar

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the pH and the pI of the polypeptide of interest need to be. See MPEP § 2173.05(c). Claims 2-18 have the limitation of claim 1 and thus are rejected on the same basis.

Claim 5 is directed to the method of claim 1, wherein the pH is adjusted to be in the range of (pH-pI) of -3 to +1. Claim 6 requires the pH to be adjusted to be in the range of (pH-pI) of -2 to -1. It is not clear what is meant by (pH-pI), it is not clear if this denotes a relationship between the pH and the pI, or if the numerical value of the pI is to be subtracted from the numerical value of pH, if so, this is not clear, as they are not equivalents to be mathematically compared. Furthermore, it is not clear how a pH can be negative, such as -3, -2, or -1.

Claim 13 is directed to the method of claim 1, wherein the mixture is incubated at 2-10°C for solubilization, preferably to 4-6°C for solubilization, in particular to 5°C for solubilization. Claim 14 is also directed to the method of claim 1, wherein the phase separating is done at 2-15°C below cloud point for extraction; preferably at 3-11°C below cloud point for extraction. The term preferably is indefinite because it is unclear whether the 'preferable' embodiments are required as part of the claimed invention. Furthermore, 'preferably' is an indefinite term because it has to do with individual perception, it is therefore not clear to whom the given ranges are preferable.

Claim 18 is directed to the method of claim 1, wherein the fermentation broth to be adjusted in step (i) is a clarified or a whole fermentation broth. It is not clear what constitutes a clarified or a whole fermentation broth. If clarified means that extraneous debris and components have been removed, it would appear whole means the debris and/or extraneous components are still present. If this is the case, the claim fails to further limit the subject matter of claim 1, as claim 18 only says the broth may or may not contain debris and/or extraneous

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components. If these are not the intended definitions of clarified and whole fermentation broths, then the true definitions are not clear, and the claim is therefore indefinite.

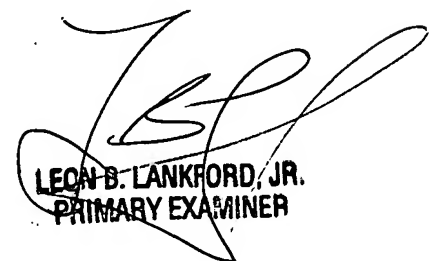
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651


LEON B. LANKFORD, JR.
PRIMARY EXAMINER